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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,781	05/04/2001	Michael Snyder	6523-028	9891
20583	7590	03/18/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,781	SNYDER ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 November 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178 and 181-192 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/08/2004 has been entered.

Status of Claims

2. Applicant's amendment filed 11/04/2004 is acknowledged and entered. Claims 108-110, 134-136, 160, 161, 163, 168, 172, 176, 179, and 180 have been canceled. Claims 1, 5, 6, 93, 162, and 164-166 have been amended. Claims 181-192 have been added.
3. Claims 1-10, 93, 108-109, and 134-135 were amended and Claims 162-180 were added by the amendment filed on 01/21/2004.
4. Claims 111, and 137 were canceled and Claims 160, and 161 were added by the amendment filed on 08/20/2003.
5. Claims 17-92, and 102-105 are canceled by the amendment filed on 4/10/03.

6. Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, and 181-192 are pending.

Election/Restrictions

7. Applicant has elected the following species for the elected invention (Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, and 181-192):

- a. A single specific species of the plurality of proteins or molecules: plurality of proteins.
- b. A single specific species of organism: a mammal.
- c. A single specific species of biological activity: kinase activity.
- d. A single specific species of solid support: a glass slide.
- e. A single specific species of interaction between the surface of the support and the substance: covalently bound.
- f. A single specific species of assaying reagent. This species is withdrawn in view of applicant argument filed 1/21/04.
- g. A single specific species of volumes of the wells: the range between 1nl and 1 μ l.

However, this election is moot with regard to the election of the solid support as being glass slide.

- h. A single specific species of the bottoms shape of the wells: round-shaped.

However, this election is moot with regard to the election of the solid support as being glass slide.

8. Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, and 175 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to *nonelected species*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement filed on 08/20/2003. Additionally, it is noted that claims 108-110, 160, 163, 168, 172, 176, and 179 are cancelled by the amendment filed 11/04/2004.

9. Thus, claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, and 181-192 are treated on the merit in this Office Action.

Priority

10. This application claims priority to two provisional applications. They are 60/201,921 filed on 5/4/2000, and 60/221,034 filed on 7/27/2000.

Withdrawn Rejection(s)

11. The rejections of claims 1-11, 134-136, 141, 161, 164, 166, 169-170, 173-174, 177-178, and 180 under 35 USC 112, first paragraph (written description) have been withdrawn in light of applicant's amendments of claim 1.

12. The rejection of claims 1-11, 134-136, 141, 161, 164, 166, 169-170, 173-174, 177-178, and 180 under 35 USC 112, first paragraph (enablement) has been withdrawn in light of applicant's amendments of claim 1.

13. The rejections of claims 1-11, 134-136, 141, 161, 164, 166, 169-170, 173-174, 177-178, and 180 under 35 USC 112, second paragraph, as being indefinite have been withdrawn in light of applicant's amendments of claim 1 and cancellation of claims 134 and 135.

14. The rejection of claims 1-11, 134-136, and 161 under 35 USC 103(a) as being obvious over Wagner et al. (US Patent 6,329,209 B1; *filings date 7/14/1999*) has been withdrawn in view of applicant's amendments of claim 1 and cancellation of claims 134-136, and 161.

15. The rejection of claims 1-11, 134-136, and 161 under 35 USC 103(a) as being obvious over Wagner et al. (US Patent 6,329,209 B1; *filings date 7/14/1999*) and Stern et al. (*Molecular and Cellular Biology*, 1991, 11(2):987-1001) has been withdrawn in view of applicant's amendments of claim 1 and cancellation of claims 134-136, and 161.

16. The rejection of claims 1-11, 134-136, and 161 under 35 USC 103(a) as being obvious over Wagner et al. (US Patent 6,329,209 B1; *filings date 7/14/1999*) and Maskos et al. (*Nucleic Acids Research*, 1992, 20(7):1679-1684) has been withdrawn in view of applicant's amendments of claim 1 and cancellation of claims 134-136, and 161.

New Rejections

17. Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, and 181-192 are treated on the merit in this Office Action.

Specification

18. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, page 31, lines 24. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, and 181-192 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm². The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila.

The specification disclosure does not sufficiently teach the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila. The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins are derived. The specification examples are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). This array clearly does not provide an adequate representation regarding the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila. Thus the specification does not teach the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, disclosed by the specification, the skilled artisan cannot envision the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making and using it. See Fiers v. Revel, 25 USPQ2d 1601,

1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification does not teach the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila. Therefore, only the yeast protein kinase array, wherein the array comprises 122 different yeast kinases, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

21. Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, and 181-192 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm². The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila.

The specification disclosure does not sufficiently teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of “*molecules comprising functional domains thereof*”), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila. The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins are derived. The specification examples are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). This array clearly does not provide an adequate representation regarding the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of “*molecules comprising functional domains thereof*”), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila. Thus the specification does not teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of “*molecules comprising functional domains thereof*”), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, disclosed by the specification, the skilled artisan cannot envision the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "*molecules comprising functional domains thereof*"), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

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diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification does not teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "*molecules comprising functional domains thereof*"), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila. Therefore, only the a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

22. Claims 1, 187, and 189-191 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm^2 . The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila. Claim 187, which depends on claim 1, recites the limitation wherein the plurality of different substances consists of one or more copies of essentially all of the kinases of an organism. Claim 189, which depends on claim 1, recites the limitation wherein the plurality of different substances consists essentially

of one or more copies of between 61 and all of the kinases of an organism. Claim 190, which depends on claim 1, recites the limitation wherein the plurality of different substances comprises all of the kinases of an organism that are encoded by nucleic acid coding sequences that are less than 4.5 kb in length. Claim 191, which depends on claim 1, recites the limitation wherein the plurality of different substances comprises all of the kinases of an organism that are encoded by nucleic acid coding sequences that can be cloned such that the kinase can be produced using recombinant DNA technology.

The specification disclosure does not sufficiently teach the claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila. The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins are derived. The specification examples are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). Furthermore, the specification discloses that "*the yeast genome has been sequenced and contains approximately 6200 open reading frames greater than 100 codons in length; 122 of these are predicted to encode protein kinases*" (i.e. there is a **possible** 122 protein kinases found in a yeast genome) (pg. 27, lines 32-34). However, this is not the **definitive** total number of protein kinases in a yeast genome since it is a **predicted** number. In fact, Hunter et al. (*TIBS*, 1992, 22(1):18-22) disclose that there is no consensus in the total number of protein kinase of a yeast genome

wherein they found a total of ~120 protein kinases, which is less than the estimate number of yeast protein kinases that was based on the sequencing of chromosome III (pg. 21, 2nd col., line 62 to 3rd col., line 5). Since there is no definitive total number of protein kinase for a yeast genome, the specification clearly does not provide an adequate representation regarding the claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila. Thus the specification does not teach the claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, disclosed by the specification, the skilled artisan cannot envision the claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes

v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification does not teach the claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila. Therefore, only the a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

23. Claims 1, 187, and 189-191 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

There are many factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any experimentation is “undue”. These factors include, but are not limited to: 1) The breadth of the claims; 2) The nature of the invention; 3) The state of the prior art; 4) The level of one of ordinary skill; 5) The level of predictability in the art; 6) The amount of direction provided by the inventor; 7) The presence or absence of working examples; and 8) The quantity of experimentation necessary needed to make or use the invention based on the disclosure. (See *In re Wands* USPQ 2d 1400 (CAFC 1988)).

(1-2) The breadth of the claims and the nature of the invention:

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm². The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and *Drosophila*. Claim 187, which depends on claim 1, recites the limitation wherein the plurality of different substances consists of one or more copies of essentially all of the kinases of an organism. Claim 189, which depend on claim 1, recites the limitation wherein the plurality of different substances consists of one or more copies of essentially all of the kinases of an organism. Claim 190, which depend on claim 1, recites the limitation wherein the plurality of different substances comprises all of the kinases of an organism that are encoded by nucleic acid coding sequences that are less than 4.5 kb in

length. Claim 191, which depend on claim 1, recites the limitation wherein the plurality of different substances comprises all of the kinases of an organism that are encoded by nucleic acid coding sequences that can be cloned such that the kinase can be produced using recombinant DNA technology.

The array comprises ***all*** of the protein kinases, i.e. known and unknown, of a single organism, and the organism includes ***any*** mammal, ***any*** yeast, or ***any*** Drosophila. Additionally, the claim further does not recites the means for determining the ***total number*** of protein kinases from a single specific species of organism wherein the total number of protein kinases from a single specific species of organism is indefinite (i.e. within the genome of a single specific species of organism the ***total number*** of a single specific species protein is unknown). Thus the claimed protein array encompasses a broad genus of protein kinases, which has yet to be identified by the specification and the state of the art.

(3 and 5) The state of the prior art and the level of predictability in the art:

The present invention relates to a broad generic of a “protein kinases array” wherein the array comprises ***all*** of the kinases of an organism, and these kinases are derived from ***any*** mammal, ***any*** yeast, or ***any*** Drosophila. The ability to determine within the genome of a single specific species of organism the ***total number*** of a single specific species protein, especially protein kinases, is unpredictable because the ***total number*** is unknown. For example, within the family of protein kinases there are distinct differences between the types of protein kinases found in multicellular organism (eukaryotic) and single cell organism (prokaryotic) because the protein kinases unique to multicellular organism would have function in cellular communication such as

between cells, tissue, and the environment would not be presence in single cell organism (see Hunter et al. (*TIBS*, 1992, 22(1):18-22): pg. 18, 1st col., lines 21-35). Furthermore, there is no consensus in the total number of protein kinase of a yeast genome wherein they found a total of ~120 protein kinases, which is less than the estimate number of yeast protein kinases that was based on the sequencing of chromosome III (Hunter: pg. 21, 2nd col., line 62 to 3rd col., line 5). Therefore, it is unpredictable to determine within the genome of a single specific species of organism the ***total number*** of a single specific species of protein kinase.

(4) The level of one of ordinary skill in the art:

The level of skill would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples.

The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins are derived. The specification examples are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). Furthermore, the specification discloses that “*the yeast genome has been sequenced and contains approximately 6200 open reading frames greater than 100 codons in length; 122 of these are predicted to encode protein kinases*” (i.e. there is a ***possible*** 122 protein kinases found in a yeast genome) (pg. 27, lines 32-34). However, this is not the ***definitive*** total

number of protein kinases in a yeast genome since it is a *predicted* number. In fact, Hunter et al. (TIBS, 1992, 22(1):18-22) disclose that there is no consensus in the total number of protein kinase of a yeast genome wherein they found a total of ~120 protein kinases, which is less than the estimate number of yeast protein kinases that was based on the sequencing of chromosome III (pg. 21, 2nd col., line 62 to 3rd col., line 5). Since there is no definitive total number of protein kinase for a yeast genome, the specification clearly does not provide an adequate representation regarding the claimed array comprising *all* of the protein kinases, i.e. known and unknown, of a single organism, and the organism includes *any* mammal, *any* yeast, or *any* Drosophila. The specification does not adequately disclose a representative number of examples of all the protein kinases within an organism (e.g. within each of the species of prokaryotic and eukaryotic there are subspecies such as rat and horse that are distinct from each other). The specification does not adequately disclose a representative number of examples of all the different type of protein kinases (e.g. the family of protein kinase there are subfamilies that are structurally and functionally distinct from one another such as the histidine protein kinases and tyrosine kinases). Therefore, the specification does not adequately disclose a representative number of examples of the claimed array comprising *all* of the protein kinases, i.e. known and unknown, of a single organism, and the organism includes *any* mammal, *any* yeast, or *any* Drosophila.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:

Accordingly, the claims are broad in scope with regard to the claimed array comprising *all* of the protein kinases, i.e. known and unknown, of a single organism, and the organism

includes *any* mammal, *any* yeast, or *any* Drosophila and the lack of specification guidance as how to determine within the genome of a single specific species of organism the *total number* of a single specific species of protein kinase would necessarily result in undue experimentation for one of ordinary skill wishing to practice the presently claimed invention.

Therefore based on the evidences as a whole regarding each of the above factors (e.g. factors 1-8), the specification, at the time the application was filed, does not satisfy the enablement requirement for the claimed array comprises *all* of the protein kinases, i.e. known and unknown, of a single organism, and the organism includes *any* mammal, *any* yeast, or *any* Drosophila.

24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claim 187 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "*one or more copies of between 61 and all kinases of an organism*" of claim 187 is indefinite because the upper limit is infinite (refers to "*all kinases of an organism*"). It is unclear as to the means of determining within the genome of a single specific species of organism the *total number* of a single specific species of protein kinase since the *total number* is unknown. Thus the upper limit is infinite for the phrase "*one or more copies of between 61 and all kinases of an organism*", and the phrase "*one or more copies of between 61 and all kinases of an organism*" of claim 187 is indefinite.

Response to Arguments

26. Applicant's arguments with respect to claims 1-11, 134-136, 141, 161, 164, 166, 169-170, 173-174, 177-178, and 180 under 35 USC 112, first paragraph (written description) have been considered but are moot in view of the new ground(s) of rejection.

The new grounds of rejections are that the specification as filed does not meet the written description provision of 35 U.S.C 112, first paragraph, regarding 1) the presently claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila; 2) the presently claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "*molecules comprising functional domains thereof*"), and these analogues are derived from *any* mammal, *any* yeast, or *any* Drosophila; and 3) the presently claimed array wherein the plurality of different substances comprises all of the kinases of an organism, and these kinases are derived from *any* mammal, *any* yeast, or *any* Drosophila.

27. Applicant's arguments with respect to claims 1-11, 134-136, 141, 161, 164, 166, 169-170, 173-174, 177-178, and 180 under 35 USC 112, first paragraph (enablement) have been considered but are moot in view of the new ground of rejection.

The new ground of rejection is that the specification as filed does not meet the enablement provision of 35 U.S.C 112, first paragraph, regarding the presently claimed array that comprises *all* of the protein kinases, i.e. known and unknown, of a single organism, and the organism includes *any* mammal, *any* yeast, or *any* Drosophila.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
March 16, 2005



PARVATHASHRI PONNALURI
PRIMARY EXAMINER